

## REMARKS

Rejected claims 95, 99, 100, 118, 124, 126, 128, 135, 144 and 151 have been cancelled without estoppel or disclaimer of the subject matter thereof.

Claims 70, 71, 73, 75-78, 80, 81, 85, 86, 88, 90-94, 96, 98, 101, 102, 104-107, 109, 117, 119, 121-123, 125, 127, 129, 130, 132-134, 136-139, 142, 143, 146, 148, 152, 153, 155-157, 159-162, 166, and 433 have been rejected under 35 U.S.C. §102(e) as being anticipated by Piplani et al. '295. This rejection is respectfully traversed with respect to these claims as amended herein.

These claims as amended herein now variously define the positioning through an opening or arteriotomy in a blood vessel of a graft assembly having a blood-conveying conduit and a flange, or struts or arms, at an end of the conduit, with defined portions oriented both within the vessel and extending through the vessel opening, as specifically defined in the claims. These claims have been amended merely to define the invention more clearly without introducing new issues not previously considered during the prosecution to date.

These aspects of the claimed invention are not disclosed or suggested by Piplani et al. '295, even during transitory conditions in the disclosed surgical sequence. Nor is there any inherent similarity in this reference to the claimed invention, since Piplani et al. '295 discloses an entirely intraluminal placement of a bifurcated graft. No blood conveying conduit extends extravascularly through an

arteriotomy or opening in a vessel, as claimed by Applicant, as a result of the surgical procedure of this reference. And, any transitory conditions that may occur between steps of the surgical procedure disclosed in this reference do not result in installation of a blood conveying conduit extending through, and extravascularly away from, an arteriotomy or opening in a vessel, in any manner resembling the claimed invention.

Specifically, regarding claim 71 as amended herein “at least a portion of each of the arms extending through the arteriotomy” finds no counterpart in the hook-like elements (207) and coil springs (203), as the Examiner contends, that are installed entirely within the blood vessel.

Similarly, regarding amended claim 117, Piplani et al. ‘295 cannot be reasonably construed as disclosing “(ii) locating a first portion ... struts within the blood vessel through the arteriotomy and in contact with an interior wall... about the arteriotomy...”, as claimed by Applicant, with “a second portion...extending outside of the blood vessel through the arteriotomy”, even during insertion of the Piplani device. This reference does not deploy hooks and springs about the insertion hole while in the transitory condition, or otherwise, of inserting the device through that hole.

And, dependent claim 123 is specifically limited to “...the struts extend radially outwardly from the orifice... with the strut assembly positioned... with the

orifice of the blood flow conduit aligned with the arteriotomy”. Hooks and springs of Piplani et al. ‘295 are not understood ever to be so deployed about the hole through which that disclosed device is deployed, even during installation or other transitory condition.

Similarly, regarding claim 142, “reconfiguring... struts... extending within the blood vessel about the opening therein, with the blood flow conduit extending through the opening for conducting blood flow away from the blood vessel”, as claimed by Applicant, is not a condition (even during installation) that can be reasonably construed from the disclosure of this reference.

Also, amended claims 109 and 153 variously recite after the advancing step, “expanding the resilient member...to a second expanded configuration about the arteriotomy within the blood vessel”. No such condition can be reasonably construed to occur in the disclosure of Piplani et al. ‘295, even during installation of the Piplani device, or other transitory conditions.

It is therefore respectfully submitted that the disclosure of Piplani et al. ‘295, both explicitly and inherently, is deficient of one or more recited steps as claimed by Applicant, and that claims 70, 71, 73, 75-78, 80, 81, 85, 86, 88, 90-96, 98-102, 104-107, 109, 117-119, 121-130, 132-139, 142-144, 146, 148, 151-153, 155-157, 159-162, 166 and 433 are not anticipated by this reference, but instead are patentably distinguishable over the cited art.

Claim 77 has been rejected under 35 U.S.C. §102(b) as being anticipated by Ersek '744. This rejection is respectfully traversed with respect to this dependent claim as amended herein.

Specifically, this claim is further limited by recitation of the number of arms that extend away from the orifice of the graft and that from the parent claim, are located "with a portion of each of the arms extending through the arteriotomy defined in the side wall of the blood vessel".

These aspects of the claimed invention are not disclosed explicitly or inherently by Ersek '744 which is understood to sever the aortic bifurcation for complete replacement by a prosthetic member. There is no arteriotomy in an intact blood vessel disclosed in this reference for anastomosing with a graft assembly in a side wall of the blood vessel, in any manner resembling Applicant's claimed invention. It is therefore respectfully submitted that the amended dependent claim 77 is now patentably distinguishable over the cited art.

Rejected claims 124, 126, 128 and 135 have been cancelled without estoppel or disclaimer of the subject matter thereof.

Claims 75, 121-123, 125, 131, 132, 134 and 136 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ersek '744 in view of Barone et al. '443. This rejection is respectfully traversed with respect to these claims as amended herein.

These claims now variously recite “with a portion of each of the arms extending through the arteriotomy defined in the side wall of the blood vessel”, or “with the strut assembly extending within the blood vessel about the arteriotomy and with the blood-flow conduit extending outwardly through the arteriotomy away from the blood vessel”.

In addition, the dependent claims are submitted to be patentable for that reason and for further recited limitations such as “the plurality of struts extend radially outwardly from the orifice of the blood flow conduit with the strut assembly positioned in the second configuration and with the orifice of the blood flow conduit aligned with the arteriotomy”, or “positioning each of the plurality of struts adjacent to an interior wall of the blood vessel and extending away from the arteriotomy after the advancing step”.

These aspects of the claimed invention are not disclosed or even suggested by the cited references considered either alone or in the combination proposed by the Examiner.

At best, these references generally disclose intravascular, or vascular replacement grafts and offer no hint or suggestion of tapping a vessel for establishing extravascular blood flow in any manner resembling Applicant’s claimed invention. Specifically, the deficient disclosure of Ersek ‘744 is discussed in the above Remarks, and Barone et al. ‘443 is similarly deficient of any

disclosure, either explicitly or inherently, of an arteriotomy for anastomosing a graft thereto to establish extravascular blood flow, in any manner resembling the steps of Applicant's claimed method. Thus, merely combining these references in the manner as proposed by the Examiner fails to establish a *prima facie* basis, including all of the claimed steps, from which a proper determination of obviousness can be made.

Nor is there any transitional condition in the disclosed procedures that suggest Applicant's claimed method, or that provide any incentive for combining these references, or even for forming an arteriotomy to establish blood flow in an extravascular graft. At best, only Barone et al. '443 discloses openings in an artery (e.g., Figures 9-11, 13 as aids to installing an intraluminal graft, but not to anastomose with an extravascular graft in any manner resembling Applicant's claimed method.

It is therefore respectfully submitted that claims 75, 121-123, 125, 131, 132, 134 and 136 as amended herein are now patentably distinguishable over the cited art.

Claims 82, 84 have been indicated to be allowable but have been objected to for depending from a rejected base claim. Claim 82 has been rewritten in independent form incorporating the base claim and intervening dependent claims,

and dependent claim 84 now depends from amended claim 82. It is therefore respectfully submitted that these claims 82, 84 are now patentable to Applicant.

Allowance of claims 108, 114, 140, 164, 165, 425-432 and 434-436 is noted with appreciation.

The above Remarks are presented in consideration of the Examiner's Response(s) to Arguments (presenting analyses of transitory conditions), and were not raised previously in support of claim amendments in the absence of such Response(s) and analyses.

The subject matter of claim amendments presented herein finds ample support in the specification, for example, in Figures 9A-19F, 20A-C, 28-33 and the associated descriptions.

Entry of this amendment, which is submitted to place this application in condition for allowance, is respectfully requested. In the event the Examiner elects to continue the rejections, he is respectfully requested to enter this amendment in order to simplify and clarify the issues for appeal. The Examiner is also invited to

contact the undersigned attorney of record regarding any remaining issues that may expedite favorable disposition of this application.

Respectfully submitted,  
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Dated: 8/22/05

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